IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION — MDL NO. 2327

THIS DOCUMENT RELATES TO
Ethicon Wave 1 cases listed in Exhibit A

PLAINTIFFS' MOTION AND MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO LIMIT OR EXCLUDE CERTAIN OPINIONS OF DEFENDANT ETHICON, INC.'S EXPERT DEBRA FROMER, M.D.

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiff submits this Motion to Limit or Exclude Certain Opinions of Debra Fromer, M.D. ("Dr. Fromer").

INTRODUCTION

Dr. Fromer is board certified in urology and female pelvic medicine and reconstructive surgery who practices in New York.[1] Ex. B. However, as an expert witness Dr. Fromer offers opinions that far exceed her field of expertise, are unsupported by the required foundation, or are simply irrelevant. This motion seeks to exclude Dr. Fromer's opinions regarding the alleged safety and efficacy of Ethicon, Inc.'s TVT device and various other opinions.

Dr. Fromer's report makes sweeping, general opinions regarding the history of treatment of stress urinary incontinence, the development and design of the TVT, the efficacy and safety of alternative devices and procedures, qualities and properties of polypropylene and other synthetic graft materials, and the accuracy and adequacy of the TVT Instructions for Use ("IFU"). Plaintiffs' now move to exclude certain opinions of Dr. Fromer pursuant to the *Daubert* standard.

LEGAL STANDARD

[1] Fromer report is attached hereto at B.

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104.[2] The trial judge acts as a gatekeeper for scientific, technical and other specialized knowledge.[3]

ARGUMENT

Dr. Fromer's medical training in the fields of obstetrics/gynecology and female pelvic medicine does not automatically render her opinions on other ancillary issues admissible. [4] Indeed, to be admissible each individual opinion he offers must satisfy the requirements of the Federal Rules of Evidence.[5] As a threshold matter, an expert witness "must have 'knowledge, skill, experience, training, or education' in the subject area in which he will testify."[6] In the context of Rule 702, knowledge "connotes more than subjective belief or unsupported speculation."[7] Trial courts must ensure that a purported expert witness "is not merely parroting the opinions of others, but that the *matters upon which she will opine are clearly within her area of expertise*."[8] One of the most fundamental prerequisites to admission of an expert's opinion is that the opinion be related to that expert's specialized knowledge.[9]

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[2] *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony).
[3] *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Kumho Tire Co., v. Carmichael*, 526 U.S. 137, 141 (1999).
[4] *See Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001).
[5] *See, e.g., Gen. Elec. Co.*, 522 U.S. at 142; *see also Daubert*, 509 U.S. at 579.
[6] *Bombardiere v. Schlumberger Tech. Corp.*, 934 F. Supp. 2d 843, 846 (N.D. W. Va. 2013) (quoting FED. R. EVID. 702).
[7] *Daubert*, 509 U.S. at 590.
[8] *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 722, 730 (E.D.N.C. 2007) (emphasis added).
[9] *See, e.g., U.S. v. Johnson*, 54 F.3d 1150, 1157 (4th Cir. 1995).

Dr. Fromer's opinions must also be based upon reliable and proper methods.[10] As this Court has recognized:

> Just because an expert may be "qualified . . . by knowledge, skill, experience, training or education" does not necessarily mean that the opinion that the expert offers is "the product of reliable principles and methods" or that the expert "has reliably applied the principles and methods to the facts of the case."[11]

The burden is on Ethicon to show that *each* of Dr. Fromer's opinions has a reliable foundation based on stated principles and methods.[12] Opinions not within Dr. Fromer's area of expertise, or not the product of reliable principles and methods, should be excluded.

I. DR. FROMER'S OPINIONS EXCEED HER QUALIFICATIONS

Dr. Fromer offered a wide variety of opinions in this matter, many of which well exceed her qualifications. As Dr. Fromer admitted at her deposition, however, she is not an expert on the following matters and any opinions related thereto must be excluded from trial:

Biomaterials and Materials Issues: Dr. Fromer admitted that she is not a polymer scientist, Ex. C. at 19:15-17[13]; has never performed bench or laboratory research on polypropylene, Ex. C. at 19:18-23; is not a biomaterials specialist, Ex. C. at 19:24-20:5. She also specified at her deposition that she was not intending to opine on the properties of polypropylene mesh outside the body, Ex. C at 20:12-17, and was not offering opinions about the biomaterials properties of Ethicon's Prolene mesh. Ex. C. at 20:18-22. Dr. Fromer further testifies that she was not opining about the effect of anti-oxidants on Ethicon's Prolene. Ex. C at 20:23-21:2. Because Dr. Fromer is not qualified to opine on any materials issues and because she

[10] *See Coleman v. Union Carbide Corp.*, 2013 U.S. Dist. LEXIS 140613, * 50 (S.D. W. Va. 2013) (holding that expert testimony must be reliable and relevant to be admissible).
[11] *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013).
[12] *See Daubert*, 509 U.S. at 597.
[13] A copy of Dr. Fromer's deposition is attached hereto as Exhibit C.

has disavowed any such opinions at her deposition, Dr. Fromer must be precluded from offering any opinions concerning Biomaterials and Materials issues at trial.

Pathology – While Dr. Fromer has offered opinions concerning the pathology of mesh specimens, including whether mesh specimens can degrade microscopically in the body, she has no qualifications to do so. As she conceded at her deposition, she is not a trained pathologist, Ex. C at 14:14-18; she has never looked at explanted polypropylene meshes under a microscope, Ex. C. at 14:22-25, 18:22-19:3; and she does not request a pathology to review her explanted mesh specimens for degradation; Ex. C at 17:24-18:9. In short, Dr. Fromer has no training in pathologically examining mesh sample, has no experience in her daily practice in either examining mesh samples or reviewing pathology reports related to degradation of mesh samples, and has not been educated in any way on the clinic-pathology correlation in mesh samples. Accordingly, to the extent that her opinions tread on any of these topics, they must be excluded.

Warnings – While Dr. Fromer initially presented herself as an expert in warnings, her deposition testimony reveals that she is not qualified to offer opinions on the adequacy of any warnings used by Ethicon on their TVT-O and Prolift products. Specifically, at her deposition, Dr. Fromer admitted that she had not written any IFUs, but claimed that she was "involved in developing warnings for a drug called Toviaz made by Pfizer." Ex. C. at 22:6-9. When pushed for specifics on her involvement, Dr. Fromer had to admit that she could not remember "the details of the conversation with regards to warnings or even with regards to the development of the materials that were given to the patient. It was eight to ten years ago, I would say." Ex. C at 24:7-11. She also could not remember whether the group even had anything to do with the drafting of the actual instructions for use that would go to

physicians." Ex. C at 24:12-15.

Furthermore, although Dr. Fromer has read IFUs in the past, she admitted that she does not rely on them consider them an important part of the information that physicians have available to them to understand the risks and benefits of a particular medical device. Ex. C at 24:24-25:9. She further opined that "surgeons should not be relying on an IFU to know what the risks, benefits, and how to use the products are." Ex. C at 25:13-15. She reiterated that point in the following question and answer from her deposition:

> Q. But I want to go back to this question about the IFU. You understand, don't you, that the IFU accompanies a medical -- there's a reason that a medical device has an IFU with it, correct?
> A. Again, the -- there may be a reason, but I do not, in my personal opinion, believe that the reason is to train doctors on how to do the surgery and to know the complications.

Ex. C at 26:11-19. Clearly, Dr. Fromer lacks the training in the drafting of the IFUs and the experience in relying on or utilizing IFUs as part of her clinical practice. Accordingly she does not have sufficient foundation to offer opinions concerning the IFU's produced by Ethicon for its Prolift and TVT-O products.

II. DR. FROMER SHOULD BE PRECLUDED FROM RELYING ON HER PATIENT POPULATION TO REACH CONCLUSIONS ABOUT THE FREQUENCY AND SEVERITY OF COMPLICATIONS ACROSS THE ENTIRE POPULATION

Dr. Fromer also offered opinions about the frequency and severity of complications from the TVT-O and the Prolift based on her experience in treating her own patient population. However, that methodology is unreliable and should be excluded under *Daubert*.

Dr. Fromer wears two hats – one as a clinician who treats women in a practice and one as an academic physician who has participated in a study on the efficacy of polypropylene mesh devices. Plaintiffs do not challenge her ability to rely on her own published literature to support

the opinions that she has offered in these cases. However, Plaintiffs do challenge her ability to use her own anecdotal stories and incomplete memory about what has happened in her clinical patient population to draw any conclusions about the frequency and severity of complications that can be seen across the entire population. This challenge is based on Dr. Fromer's own testimony that she does not use the same methodology to track and record complications in her clinical patient population:

> Q There's a group of patients that you followed for the article that you published in 2015, correct?
> A. That's correct.
> Q And there was a methodology that you used for qualifying those patients for the study that you were doing, correct?
> A Correct.
> Q And there was a methodology that you used for tracking the outcomes for those patients, correct?
> A Correct.
> Q And there was a methodology that you used to do the statistical analysis to look at what the outcomes of those patients were, correct?
> A Correct.
> Q You don't do that for the rest of your patient population, correct?
> A Correct, but I don't need to tell you how many transfusions in all the patients I've done have been.
> Q. I'm not focusing just on transfusions. I want to get an idea of what you do across the hundreds of women that you've implanted. And so, apart from those who have been reported in the Canadian Urology Journal, you don't follow the methodology for selection for tracking and for statistical analysis across your clinical population, correct?
> A Not in the past. However, this is not -- this is not a -- these are not long-term complications. This is an intraoperative complication. Are we just talking generally?
> Q I'm just talking generally.
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> ***
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> We've already discussed that there was a particular way that you undertook the methodology for the Canadian Urology Journal. You don't employ that same methodology for considering, including, tracking, and analyzing your clinical outcomes in your typical clinical patient who comes in, correct?
> A. That's correct.
> Q That doesn't exist. So what does exist is the study that you did that was published?
> A Correct.

> Q And that's the only place that I could get the statistical analyses that would look at these different rates of complications across your clinical population?
> A Correct.

Ex. C at 110:14-111:19; 112:7-20. Because Dr. Fromer has not used any methodology, let alone a reliable one, to track complications (including frequency and severity) in her own clinical population, she should be precluded from relying on that experience to reach conclusion about the frequency and severity of complications across the broader population.

III. DR. FROMER MUST BE PRECLUDED FROM TESTIFYING THAT MECHANICALLY CUT MESH AND LASER CUT MESH HAVE THE SAME CLINICAL PERFORMANCE.

Dr. Fromer must also be precluded from offering the opinion that mechanically-cut mesh performs the same clinically as laser-cut mesh. When pushed for the basis of that opinion in her deposition, Dr. Fromer responded as follows:

> Q. Is there data to support your conclusion that there is no difference between the risk profile of the laser-cut mesh and the mechanically-cut mesh?
> A. There is no data to support it or to not support it. It doesn't exist.

Ex. C at 150:20-24. *See also* Ex. C at 152:5-9 ("Q. What data do you have to support your hypothesis that the laser-cut mesh performs the same as the mechanically-cut mesh? A. There is no data to support one over the other.")

Upon further questioning, Dr. Fromer conceded that her opinion was not based in literature, but her own anecdotal observations in her patient population. Ex. C at 151:24-152:2 ("A Over the years, we have -- our hospital has switched from a mechanical-cut mesh to a laser-cut mesh. I have noticed no difference in outcomes with respect to either one.") However, not only does that basis fail for the reasons set forth in Section II, *supra*, it fails separately because Dr. Fromer admitted that prior to March 28, 2016, she didn't even know whether the mesh she was using was laser cut or mechanically cut:

> Q. Fair enough. How do you know whether you're using a mechanically-cut or a laser-cut TVT?
> A. We look at the box. In fact, I didn't know up until yesterday when I looked at the box.
> Q. Okay. So prior to -- I don't know what today is. Prior to March 28, 2016, you didn't know when you implanted a TVT into a woman, TVT or a TVT-O, whether you were using a laser-cut or mechanically-cut, correct?
> A. That's because I believe it's irrelevant.
> Q. And that's not based on any data, though?
> A. There is no -- there is no data to support one is better than the other.

Ex. C at 154:8-20. In other words, Dr. Fromer has absolutely no basis for opining that the mechanically-cut mesh and the laser-cut mesh perform the same clinically – she has not literature she can point to and she doesn't have any knowledge on the types of products that she has implanted. Her words speak volumes – "because I believe it's irrelevant" is simply not an adequate basis for offering opinions to the jury without any foundation or basis whatsoever. For that reason, these opinions must be excluded.

CONCLUSION

For the foregoing reasons, Dr. Fromer's opinions do not meet the requirements for admission under *Daubert* and FED. R. EVID. 702, 403 and 104. Accordingly, her opinions in this case must be excluded, or at least limited.

This 21st Day of April, 2016

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